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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,277	09/01/2006	Charles E. Brown III	B1075.70043US01	1604

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,277	BROWN ET AL.	
	Examiner	Art Unit	
	Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *28-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/17/08; 9/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of the invention of Group I, claims 1-27 in the reply filed on August 21, 2008 is acknowledged. Claims 28-65 are withdrawn as being directed to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: the Brief Description of the Drawings fails to provide a description for Figures 6A, 10A, 11A-11D, 12A, 12B, 15A, 15B, 16A-16C, 19A, 34A, 34B and 41A-41E.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kagan et al (5,311,866).

Kagan et al disclose a device comprising a catheter (10) having a handle (i.e. proximal end) and a shaft portion (12) coupled to the distal end of the handle. There is also a tip portion (30) and a braided conductive member (16) coupled to the tip and shaft portions. A mandrel (32 - as shown in Figure 4) extends through the shaft and attaches to the tip portion, wherein actuation of the mandrel causes the braided member

to expand and contract. The braided member includes insulated regions and uninsulated (24) portions (col. 3, lines 15-25) providing electrically independent portions that do not contact each other (see Figures). The mandrel is slidably disposed in the shaft and through the handle (i.e. proximal end of sheath) and coupled to an actuator (shown as a ring) that is used to move the mandrel proximally to expand or deploy the braided member or moved distally to compress the braided member.

Claims 1, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by McGee et al (5,891,136).

McGee et al disclose a device comprising a catheter (Figure 1) having a handle (18) and a shaft portion (12) attached to the handle. A tip member (20) is provided at the distal end of the catheter and a braided conductive member (50 – Figure 8) is coupled to the shaft and tip portions. A mandrel (76 – Figure 14) is fixedly attached to the tip member (66) and disposed slidingly within the shaft portion to actuate the tip member between contracted and expanded positions. The mandrel is connected to an actuator in the handle (shown in Figure 1) to control the movement of the mandrel.

Claims 1, 4-15, 20 and 23-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Collins et al (2002/0107511).

Collins et al disclose a catheter device comprising a handle (10) and a shaft portion (12) extending from the handle (Figure 1). A tip portion (18) is located at the distal end with a braided conductive member (28) coupled to the shaft portion and the

tip portion. A mandrel is attached to the tip portion to control expansion and compression of the braided member (col. 5, lines 14-23). The braided electrode member has insulated (34 - Figure 6A) and uninsulated (50) portions such that a plurality of electrically independent portions are created. The mandrel extends within the handle portion and is connected to an actuator that is used to control steering of the device as well as deployment of the braided member. The tip portion of the device includes a cap portion (20) and an anchor portion (24) whereby the mandrel may be secured to the anchor portion to control movement of the braided member (col. 5, lines 14-23). Collins et al further disclose providing the mandrel (100 – Figure 18) with a plurality of lumens to provide fluid to a distal end of the tip member as well as along the length of the mandrel. The fluid lumen extends to the handle portion and is in fluid communication with a fluid port (120) connected to the handle member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2, 3 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al (‘866), McGee et al (‘136) or Collins et al (‘511) references and further in view of the teaching of Cox (5,868,706).

The Kagan, McGee and Collins references have all been addressed. All three include a mandrel for deployment of a braided member. However, none of these references explicitly disclose a mandrel having different diameters along the length.

With regard to the particular material used to make the catheter tip (i.e. applicant's claims 20-22), the examiner maintains that those of ordinary skill in the art are fully aware of the various types of elastomeric materials used in making catheters. Moreover, McGee et al expressly teach the use of silicone and other elastomeric materials in making the catheter (col. 7, lines 60-65). The use of any of these materials in making the tip section is deemed an obvious selection of known materials for one of ordinary skill in the art.

Regarding claims 2 and 3, Cox discloses another catheter device having a mandrel (24) for controlling movement and actuation of the catheter. In particular, Cox teaches that it is known to provide varying flexibility along the length of the device by providing varying diameters along the length of the mandrel (col. 2, lines 41-44).

To have provided any of the Kagan, McGee or Collins devices with a mandrel having varying thicknesses along its length to vary the flexibility along the length of the catheter would have been an obvious design modification for one of ordinary skill in the art since Cox fairly teaches it is known to provide such a mandrel in a catheter body for the same purpose.

Claims 4-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al ('136) in view of the teaching of Collins et al ('511).

McGee et al fails to disclose electrically isolated electrode regions as well as insulated regions along the braided structure, and further fail to disclose the provision of a fluid through the mandrel to the vicinity of the braided member. It is noted that McGee et al do disclose a fluid port (36) on the handle for providing fluid through a central member (142 - Figure 15E).

As asserted above, Collins et al disclose the use of insulated regions and electrically uninsulated regions located on the braided conductive for providing a plurality of electrically independent regions to treat a plurality of different tissue areas. Further, Collins et al teach that it is known to provide a fluid through the mandrel member to deliver fluid along the length of the braided conductive member.

To have provided the McGee et al device with a plurality of insulated and uninsulated regions to provide a plurality of electrically independent regions for treatment of multiple tissue sites would have been an obvious modification for the skilled artisan since Collins et al teach it is advantageous to provide such an arrangement in an analogous device. To have further provided the McGee et al mandrel with a fluid passage to provide fluid to the expandable braided device would have been an obvious consideration to the skilled artisan, particularly since McGee et al already disclose the provision of a fluid lumen to an expandable member and further since Collins et al teach it is known to provide such a passage through the mandrel.

Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over he Kagan et al (‘866) in view of the teaching of Collins et al (‘511).

Kagan et al fails to disclose providing a fluid lumen through the mandrel for providing fluid to the conductive braided member. Collins et al teach that it is known to provide a fluid through the mandrel member to deliver fluid along the length of the braided conductive member.

To have provided the Kagan et al device with a fluid passage to provide fluid to the expandable braided device would have been an obvious consideration to the skilled artisan since Collins et al teach it is known to provide such a passage through the mandrel for the same reason.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al ('866), McGee et al ('136) or Collins et al ('511) references and further in view of the teaching of Liprie et al (WO 99/15255).

Kagan, McGee et al and Collins et al all fail to disclose the specific material used in making the mandrel. The examiner maintains that the use of shape memory materials, such as NITINOL, in the formation of catheter components, including mandrels, is well-known in the art. In support of this assertion, attention is directed to Liprie et al who disclose an analogous catheter device having a mandrel, whereby the mandrel is made from NITINOL or other superelastic materials (page 6, lines 22-28).

to have formed the Kagan, McGee et al or the Collins et al mandrels from any known material, such as superelastic materials to provide sufficient flexibility to the device, would have been an obvious design consideration for one of ordinary skill in the

art since Liprie clearly teaches the use of such materials for making mandrels in catheter devices.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Kagan et al ('866), McGee et al ('136) or Collins et al ('511) references and further in view of the teaching of Imran et al (5,813,997).

None of the Kagan, McGee or Collins devices specifically disclose a dielectric coating on the mandrel member. Imran et al disclose a guidewire device (i.e. mandrel), and specifically teach that it is known to provide the mandrel with a dielectric coating (col. 11, lines 10-18), particularly given that the mandrel is used in an electrosurgical device.

To have provided any of the Kagan, McGee or Collins mandrels with a dielectric coating to prevent interference with the conductive regions on the expandable braided member would have been an obvious design consideration for one of ordinary skill in the art since Imran et al fairly disclose the use of dielectric coatings on mandrels used in electrosurgical applications.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gambale et al (6,315,778), Falwell et al (7,255,695) and Laptewicz et al (5,653,684) disclose other catheter devices having conductive braided members at the distal end.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
March 10, 2009